4378 FIRST AID KIT- 4378 first aid kit
Honeywell Safety Products USA, INC

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

4378 First Aid Kit (FABC, EW, aypanal EX, BZK wipes, Sting relief - Z63158000)

BZK
Active ingredient

Benzalkonium chloride 0.13% w/v

BZK
Purpose

First aid antiseptic

BZK
Uses

Antiseptic cleansing of face, hands, and body without soap and water

BZK
Warnings

For external use only

Do not use
- in the eyes or over large areas of the body
- on mucous membranes
- on irritated skin
- in case of deep puncture wounds, animal bites or serious burns, consult a doctor
- longer than 1 week unless directed by a doctor

Stop use and ask a doctor if
- if irritation, redness or other symptoms develop
- the condition persists or gets worse

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

BZK
Directions

tear open packet and use as a washcloth

BZK

Other information

- store at room temperature 15 ^{0} to 30 ^{0} C (5 ^{0} - 86 ^{0} F)
- do not reuse towelette

BZK
Inactiave ingredient

water

BzK
Questions

1-800-430-5490

Aypanal
Active ingredient (in each tablet)

Acetaminophen 500 mg

Aypanal
Purpose

Pain reliever/fever reducer

Aypanal
Uses

- temporarily relieves minor aches and pains due to the common cold and headache
- temporarily reduces fever

Aypanal
Warnings

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4,000 mg in 24 hours, which is the maximum daily amount.
- with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription).
- If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

- liver disease

Ask a doctor or pharmacist before use if

- you are taking the blood thinning drug warfarin

Stop use and ask a doctor if
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

If pregnant or breastfeeding
- ask a health professional before use.

Keep out of reach of children.

Keep out of reach of children.

Overdose warning: In case ofl overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Aypanal
Directions
- **do not take more than directed (see overdose warning)**
- adults and children 12 years of age and over: Take 2 tablets with water every 6 hours while symptoms last.
- do not take any more than 8 tablets in 24 hours.
- children under 12: consult a doctor

Aypanal
Other information
- store at room temperature 15^{0} -30^{0} C (59^{0} -86^{0} F)
- TAMPER EVIDENT- DO NOT USE IF OPEN OR TORN

Aypanal
Inactive igredients

microcrystalline cellulose, povidone, sodium starch glycolate, starch, stearic acid

Aypanal
Questions or Comments

1-800-430-5490

FABC
Active ingredient

Benzalkonium chloride 0.13%

Lidocaine HCl 0.5%

FABC
Purpose

First Aid antiseptic

External analgesic

FABC
Uses
- prevent skin infection
- for temporary relief of pain associated with minor burns

FABC
Warnings

For external use only

Do not use
- in or near the eyes
- if you are allergic to any of the ingredients
- lin large areas of the body, particularly over raw surfaces or blistered areas
- for more than 10 days

Ask a doctor before use if you have
- deep or puncture wounds
- animal bites
- serious burns

Stop use and ask a doctor if

- condition worsens
- symptoms persist for more than 7 days or clear up and occurs again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away.

FABC
Directions
- **adults and children 2 years of age and older:**
- clean the affected area
- apply a small amount of this product (equal to the surface area of the tip of a finger) onto affected area 1 to 3 times daily
- may be covered with a sterile bandage
- **children under 2 years of age: consult a doctor**

FABC
Inactive ingredients

aloe barbadensis juice, cetyl alcohol, diazolidinyl urea, edetate disodium, glycerin, glyceryl stearate SE, methylparaben, mineral oil, PEG-100, propylene glycol, propylparaben, stearic acid, trolamine, water

FABC
Questions

1-800-430-5490

Sting Relief
Active ingredient (in eachwipe)

Ethyl alcohol 50.0%

Lidocaine HCl 2.0%

Sting Relief
Purpose

Antiseptic

Topical pain relief

Sting Rellief
Uses

- prevent infection in minor scrapes, and temporary relief of itching of insect bites

Sting Relief
Warnings

For external use only

Flammable, keep away from open fire or flame

Do not use

- over large areas of the body
- in eyes
- over raw or blistered areas

Stop use and ask a doctor

- if conditions worsen or persist for more than 7 days or clear up and occur again within a few days

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Sting Relief
Directions

- adults and children 2 years and older: Apply to cleaned affected area not more than 3 times daily.
- children under 2 years of age: consult a doctor.

Sting Relief
Inactive ingredients

benzalkonium chloride, menthol, and purified water

Sting Relief
Questions or Comments?

1-800-430-5490

4378
Z631580000 KIT CONTENTS

1 INSTANT COLD PACK 4" X 6"

1 ADHESIVE TAPE W/P 1/2"X 5 YD

1 TWEEZER PLASTICS 4"

1 FIRST AID GUIDE ASHI

1 ABD COMBINE PAD 5" X 9"

1 CPR FILTERSHIELD 77-100

1 FIRST AID BURN CREAM 0.9 GRM PKT 20

1 SCISSOR BDGE 4" RED PLS HDL

1 FANNY PACK RED FAK LOGO EMPTY

1 LBL STOCK 4"X2-7/8"

1 LBL STOCK 3"x1-7/8"

6 BZK ANTISEPTIC WIPE, BULK

1 1 PR LRG NITRILE GLVES ZIP BAG

1 1" X 3" PLASTIC BANDS 16/BAG

5 SAFETEC STING RELIEF WIPES BULK

1 TRI BNDG NON WOVEN 40"X40"X56"

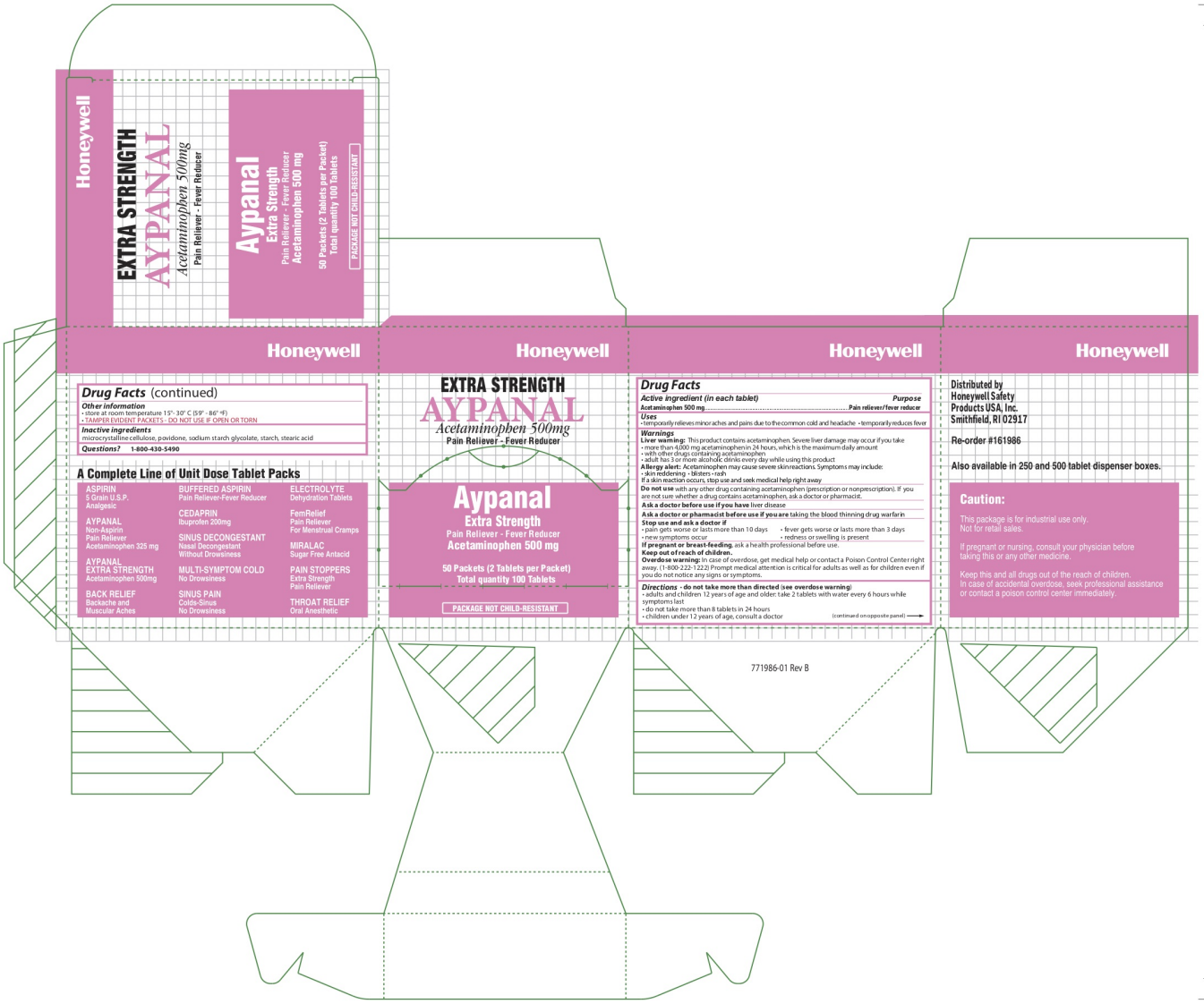
3 GAUZE PADS 3"X3" 12PLY

2 HEAVY FLEX LARGE PATCH 2" X 3"

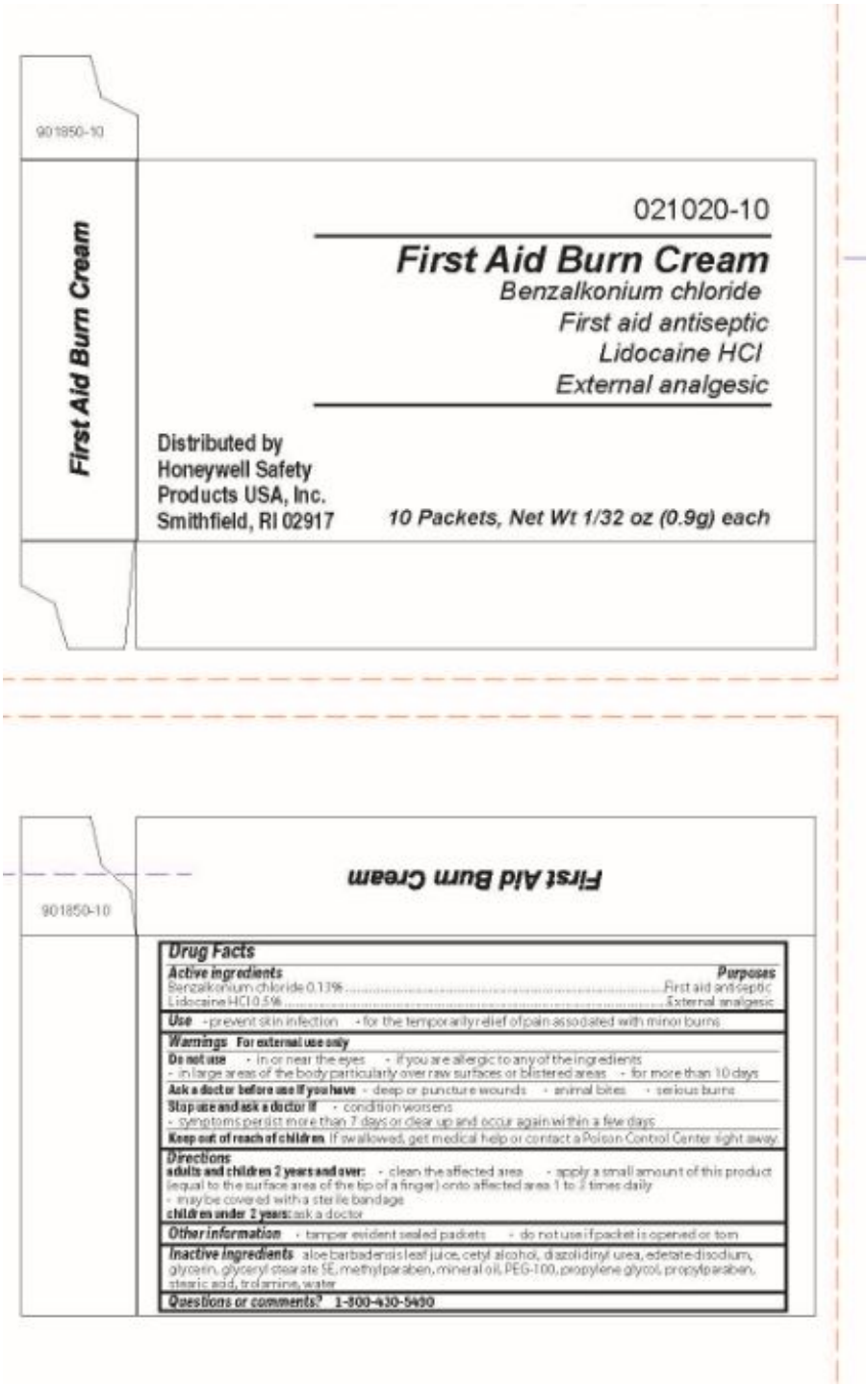
2 AYPANAL EXTRA BULK 2/PK

BZK
Principal Display Panel

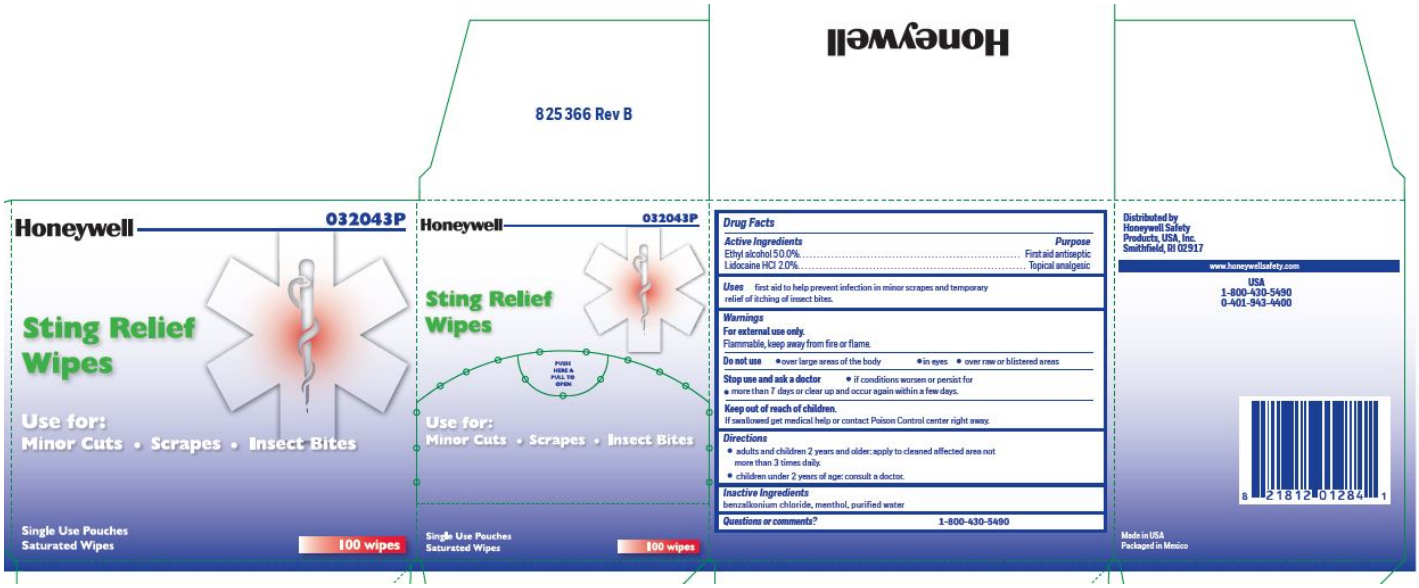
Aypanal
Principal Display Panel



FABC
Principal Display Panel



Sting Relief
Principal Display Panel



4378 Kit Label
Z631580000

Distributed by Honeywell Safety Products USA, Inc. Smithfield, RI 02917

APPROVED
By Rodrigo Rosas Arllano at 2:58 pm, Mar 11, 2019

4378 FIRST AID KIT

4378 first aid kit kit

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0498-4378

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-4378-01	1 in 1 KIT; Type 0: Not a Combination Product	10/18/2018	

Quantity of Parts		
Part #	**Package Quantity**	**Total Product Quantity**
Part 1	5 POUCH	2 mL
Part 2	6 PACKET	8.4 mL
Part 3	2 PACKET	4
Part 4	20 PACKET	18 g

Part 1 of 4

STING RELIEF PAD

ethyl alcohol, lidocaine swab

Product Information	
Item Code (Source)	NDC:0498-0733
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE ANHYDROUS	20 mg in 1 mL
ALCOHOL (UNII: 3K9958V90M) (ALCOHOL - UNII:3K9958V90M)	ALCOHOL	0.5 mL in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
MENTHOL (UNII: L7T10EIP3A)	
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1		0.4 mL in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part348	12/23/2017	

Part 2 of 4

ANTISEPTIC TOWELETTE

benzalkonium chloride liquid

Product Information

Item Code (Source)	NDC:0498-0501
Route of Administration	TOPICAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	1.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0498-0501-00	1.4 mL in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333E	12/22/2017	

Part 3 of 4

AYPANAL EX

acetaminophen tablet

Product Information

Item Code (Source)	NDC:0498-2110
Route of Administration	ORAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients	
Ingredient Name	**Strength**
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics			
Color	white	**Score**	no score
Shape	ROUND	**Size**	12mm
Flavor		**Imprint Code**	FR1
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0498-2110-01	2 in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/02/2017	

Part 4 of 4

FIRST AID BURN

benzalkonium chloride, lidocaine hydrochloride cream

Product Information	
Item Code (Source)	NDC:0498-0903
Route of Administration	TOPICAL

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7) (BENZALKONIUM - UNII:7N6JUD5X6Y)	BENZALKONIUM CHLORIDE	0.13 g in 100 g
LIDOCAINE HYDROCHLORIDE (UNII: V13007Z41A) (LIDOCAINE - UNII:98PI200987)	LIDOCAINE HYDROCHLORIDE	0.5 g in 100 g

Inactive Ingredients	
Ingredient Name	**Strength**
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
WATER (UNII: 059QF0KO0R)	
LIGHT MINERAL OIL (UNII: N6K5787QVP)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
TROLAMINE (UNII: 9O3K93S3TK)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
DIAZOLIDINYL UREA (UNII: H5RIZ3MPW4)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1		0.9 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	12/20/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/18/2018	

Labeler - Honeywell Safety Products USA, INC (079287321)

Establishment

Name	Address	ID/FEI	Business Operations
Honeywell Safety Products USA, INC		079287321	pack(0498-4378)

Establishment

Name	Address	ID/FEI	Business Operations
Ultra Seal Corporation		085752004	manufacture(0498-2110)

Establishment

Name	Address	ID/FEI	Business Operations
Water-Jel Technologies		155522589	manufacture(0498-0903)

Establishment

Name	Address	ID/FEI	Business Operations
Changzhou Maokang Medical		421317073	manufacture(0498-0501)

Establishment

Name	Address	ID/FEI	Business Operations
Safetec of America Inc		874965262	manufacture(0498-0733)